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COMMISSION STAFF WORKING PAPER

Results of the public consultation "TOWARDS A STRATEGIC VISION OF LIFE SCIENCES AND BIOTECHNOLOGY"

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FOREWORD[1]

On 23 January 2002, the Commission presented a Communication entitled "Life Sciences and Biotechnology – A Strategy for Europe" (COM(2002) 27 final), thus fulfilling its undertaking given in March 2001 at the Stockholm European Council as part of the Lisbon process to produce strategic guidelines accompanied by concrete actions. In accordance with its governance policy, the Commission prepared for this Communication by conducting a public consultation, in the context of which it collected many reactions, opinions and suggestions. These are shown in this document but do not in any way reflect the Commission's position in this matter.

The main steps in the public consultation

The public consultation was held between 4 September and 23 November 2001 and was based on a supporting text[2] which tackled all the issues associated with biotechnology, raised the main questions and asked for comments and opinions. This document, available in 11 languages, was placed on the website created for this purpose in July 2001 (http://europa.eu.int/comm/biotechnology).

Contributions could be submitted by post, fax or e-mail. If they were no longer than two pages and written in either English, French or German, they could be published on the website. Other information was also available on the site, in particular the provisional programme for the consultative conference of stakeholders on 27 and 28 September 2001 and, after the conference, summary reports on each of the four workshops.

The consultative conference was attended by almost 320 participants from the scientific world, consumer and environmental protection associations, the media, biotech and health companies. Political decision-makers from the EU institutions, the Member States, candidate countries and other countries, including developing countries, were also there. Forty high-level speakers, including MEPs and five Commissioners, spoke at its six working sessions.

The aim of this report is to analyse the 316 contributions received in response to the points and questions in the consultation document.

The wide range of opinions and proposals made reflects the extent of the areas covered by the consultation document. The chosen structure is based on the most commonly expressed ideas and could certainly be challenged; without claiming to be exhaustive, the document tries to reflect, as objectively as possible, the richness and variety of the contributions received. In its desire for transparency, the Commission plans to make these contributions available to the public. The table in the Annex shows a breakdown of respondents by type of contributor and country.

The first part of the document makes some general comments and analyses the themes most often brought up by the various sectors.

The second part lists the ideas most often mentioned and classifies them under three headings: points of consensus, points of debate and points of conflict. "Ideas" in this context means

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1 Only the French version is authentic.

2 "Towards a Strategic Vision of Life Sciences and Biotechnology" (COM 454 of 04/09/2001).

opinions and suggestions for action. The last heading refers to a small number of subjects where the issues were fundamental and the positions taken too polarised for compromises or technical solutions to be found. The last two groups were not taken together so that they could be studied and discussed in more depth in order to come up with options and choices at European and other levels which could lead to constructive work and approaches leading to results. Please note that the figures in brackets refer to the registration numbers of the contributions.

The third part of the document provides some information about how the contributions have been taken into account. However, a more systematic follow-up is planned, and many of the ideas shared during the consultation will be taken up again later on in more depth in other contexts.

Please note that the figures in brackets refer to the registration numbers of the contributions. However, where a figure is underlined, it refers to an actual number, not to a registration number.

PART I GENERAL CONSIDERATIONS

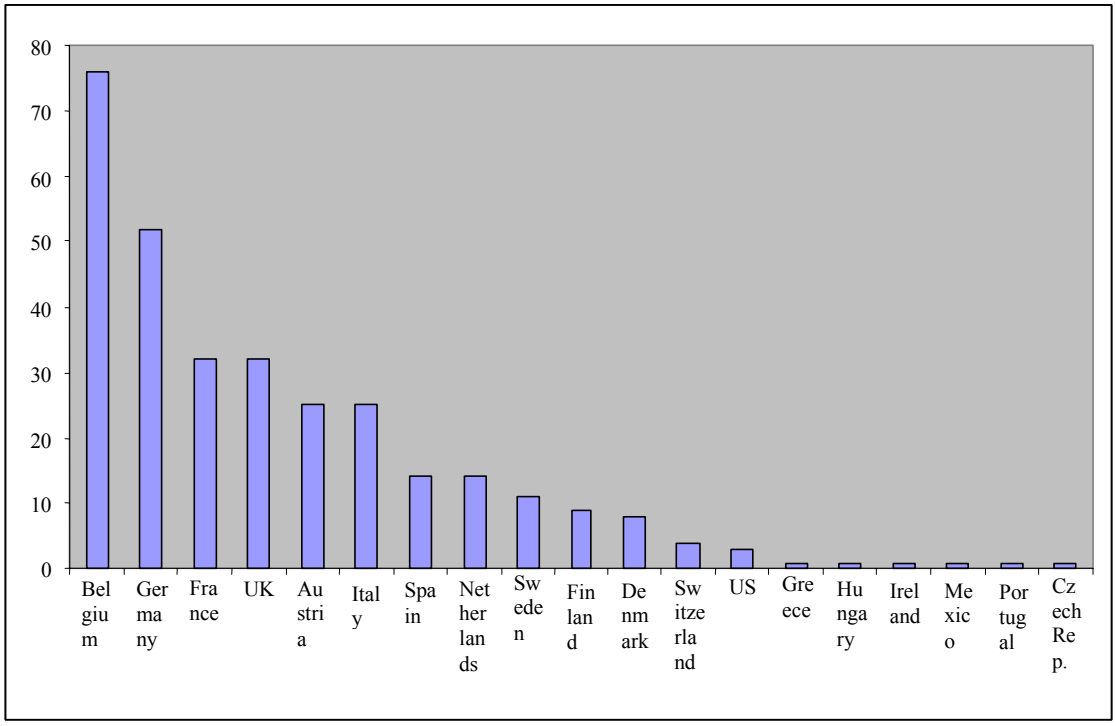
A. The consultation was welcomed with interest but did not escape criticism

The consultation was received with interest, because the debate suffers from an extreme level of polarisation (299). Some people thought that the consultation had been conducted too late, concomitant with other consultations and over far too short a period (205, 225). Some thought that the consultation document did not take the ecological dimension sufficiently into account (59), that the precise objective of the future European strategy had not been explained in enough detail (208, 210), that the scope was too wide (274), or that the term "genetic sciences" would have been more appropriate than "biotechnology" (70, 71, 243). The “secrecy” of the consultation - because the Commission had not publicised it sufficiently - was also criticised by several respondents (50, 105, 138, 150, 159). Some criticised that only contributions in English, German or French would be published on the website. It should be noted here that some messages sent by e-mail were nevertheless written in Italian, Spanish or Finnish and that, in any case, contributions sent by post (which could not be published on the website) were not subject to this restriction.

B. The number of contributions received per country differed widely, and not all the contributions were published on the website

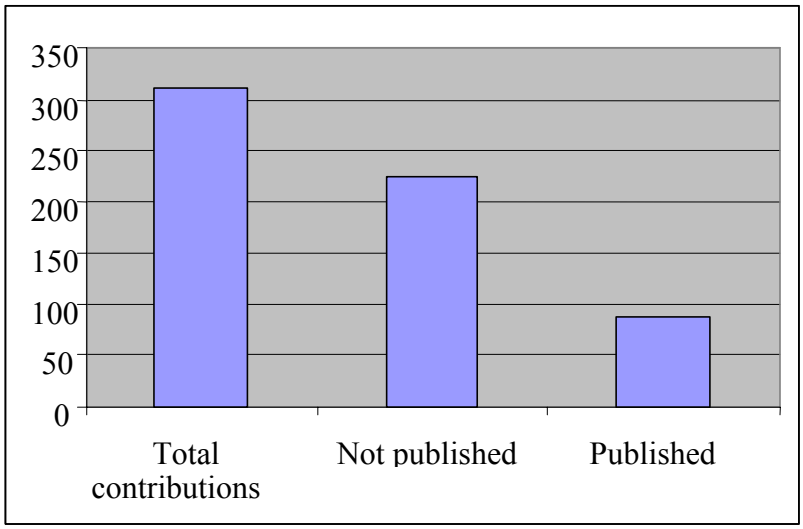
Six countries provided by far the greatest number of contributions: Belgium, Germany, France, the UK, Austria and Italy. The over-representation of Belgium is probably linked to the presence of many professional organisations and NGOs in Brussels and their European outlook. It should be noted that the number of contributions from the four ‘cohesion countries’ (Spain, Portugal, Ireland and Greece) was extremely low. It is impossible to say whether this is the result of a lack of equipment, deficiencies in the circulation of information, cultural factors which mean that people in these countries tend to respond to other ways of consultation and expression, fears about the use to which contributions could be put or a combination of several of these factors, but the representativeness of the results seems to be somewhat distorted.

Fig. 1 : Contributions received per country



Another characteristic of the responses received was the large number (223) that could not be published on the website because they were longer than 2 pages[3]. Some large public research organisations and consortia of private companies submitted very extensive files. The consultation exercise was therefore able to extensively document this area both at technical/scientific level and at sociological, economic and ethical levels.

Fig. 2 : Contributions published and not published



[3] The Commission is currently seeking the consent of persons who submitted their comments by letter or fax for these contributions to also be published on the Internet.

C. The polarisation of interests on certain topics depending on the type of contributor

1. Private citizens

With regard to the many (117) contributions submitted by ordinary people (individuals), it should be noted that many of these people speaking in a personal capacity did in fact hold specific professional posts (experts, directors of consumer associations, researchers, etc.). They should therefore not necessarily be taken as reflecting the opinions of "ordinary people", i.e. the uninformed. As a consequence, the opinions expressed by individuals do not constitute a category of their own but can be grouped under one of the six headings below.

2. Representatives of the academic world

As a rule, these contributors were in favour of the prospects offered by biotechnology, whilst recognising the risks and therefore the need to establish rules and define a political strategy for better risk evaluation and guaranteeing safety. Their contributions related mainly to the conditions under which research should be organised and funded and the subjects to be promoted. They therefore constitute a specific interest group.

3. NGOs and civil society organisations

With regard to non-governmental organisations (NGOs), two main groupings can be distinguished: religious organisations and other NGOs.

Whilst the former focused on the ethical issues, the latter were concerned about the risk of making developing countries even more dependent than they are now, protecting the environment and preserving bio-diversity, as well as food safety.

The most common demand was for freedom of choice for individuals (right to old age, right to life, right to a "natural" death, rejection of any form of euthanasia, respect for the dignity and integrity of human beings) or for consumers to be maintained.

Environmentalists' contributions were more in keeping with modernity; they were therefore more a matter of debate than of conflict.

4. Biotechnology groups

Biotechnology groups and, more generally, business representatives tended to praise the positive spin-offs of biotechnology development for the economy, health and the environment, with regard to developing countries, too. They were more interested in amending regulations and harmonising norms with European standards so as to close some of the competitive gap that has opened up between Europe and the United States.

5. Public and semi-public organisations

Public and semi-public organisations, mainly from northern Europe, spoke about the changes that needed to be made to the regulations and the shortcomings of the 5th and 6th RDFPs (Research and Development Framework Programmes). Demonstrating their experience of risk management and governance, they adopted a fairly confident attitude towards the development of biotechnology and the ability of the public authorities to keep pace with it.

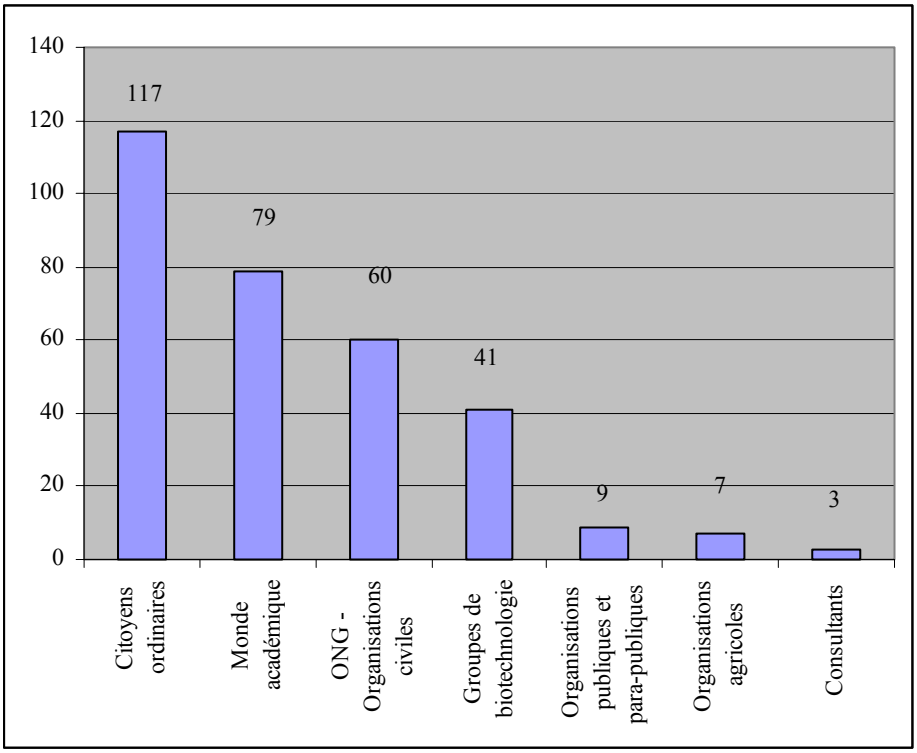
6. Farming organisations

Farming organisations were worried about genetically modified organisms (GMOs), the risk of their contaminating conventional crops, the impossibility of guaranteeing the harmlessness of imported seeds and produce (soya and maize). They were opposed to farmers having to pay additional costs to create watertight procedures and their being held responsible for any contamination.

7. Consultants

Consultants were interested mainly in risk evaluation and management procedures, information and public consultation mechanisms and the opportunities offered by the European research programmes.

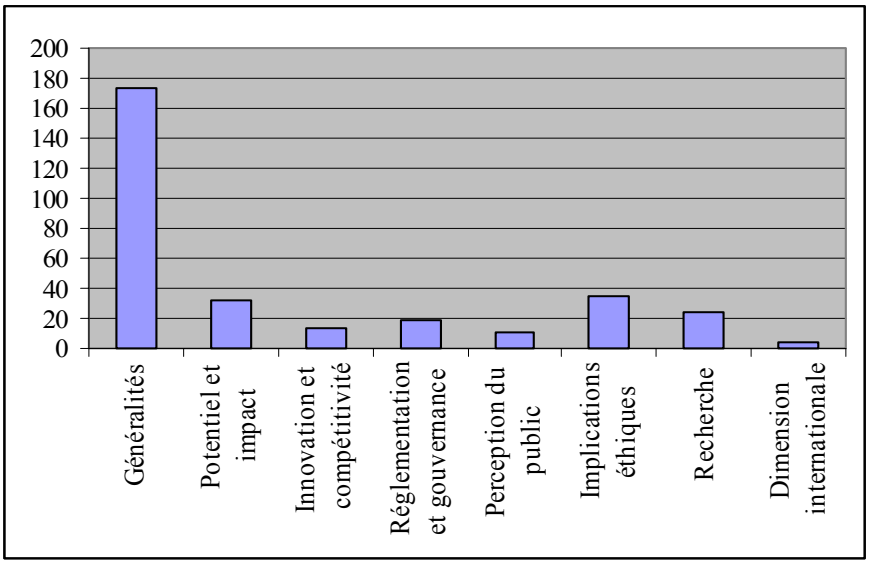
Fig. 3 : Contributions by type of contributor



D. Predominance of general contributions

Many of the contributions answered the questions raised in a detailed, well argued and sometimes exhaustive way. A large proportion of them can only be categorised as "general contributions" because their authors did not identify them as coming under one of the specific headings in the consultation document. The highest number of contributions related to the ethical implications, followed by the opportunities and impact of biotechnology, and opinions relating to research.

Fig. 4 : Contributions by field, as laid down in the consultation document



PART II CLASSIFICATION OF THE ARGUMENTS IN THREE CATEGORIES: POINTS OF CONSENSUS, POINTS OF DEBATE, POINTS OF CONFLICT (DEEP DISAGREEMENT)

A Points of consensus

The points grouped under this category are those ideas and suggestions that tended to be universally shared. They include 'common sense' arguments and some technical suggestions that are not controversial. To a certain extent, they represent the viewpoint of the "honest man" who recognises the potential benefits of technical progress but also the need to provide a framework for it.

1. Mobility of scientists and research policy

Mobility of scientists and better working conditions and pay (138, 155, 181, 184, 208, 213, 218, 240, 250, 256, 262). Stepping up the Marie Curie programme, improving career opportunities and coordination actions at European level (35, 120, 197). Greater recognition from society (121), stepping up and better allocating the appropriations awarded to research (basic research (49, 84, 250), applied research (135) and risk evaluation (49)). Encouraging enterprise among researchers (135, 155, 195, 214, 244, 315), in universities (249) and welcoming researchers from outside the EU (180).

Developing research and technological potential: avoiding duplication of effort by means of a European database (92, 214). Promoting interfaces between universities, research centres and businesses (8, 67, 180, 192, 197, 215, 240). The European Union should conduct a regular survey of industry and research needs (227) and facilitate coordination between the national research bodies (277, 287). Creation of a trans-European network of centres of excellence and technology transfer (84, 138). However, the impact on employment must not be overestimated (194, 278).

2. Businesses and competitiveness

Developing SMEs in the biotechnology sector: the main limitations are the lack of trained technicians and scientists, directors and managers (158, 180, 197). Lack of own resources for research (121, 240) and development (158). Administrative burdens and lack of tax breaks for business start-ups and investors in the European Union (84, 183, 240, 276).

Competitiveness of Europe: An important goal (117, 138, 148, 155, 157, 183, 200, 214, 216, 227, 255, 286), developing centres of excellence (180, 208), facilitating rapid decision-making at EU level (208) and guaranteeing that the same binding rules are respected by neighbouring countries too (208), creating a favourable and stimulating environment for innovation, start-ups (195, 278, 293) and companies in general, in particular in the area of taxation (98, 158, 192, 254, 271). The patent system must become cheaper and more effective, managed centrally at EU level (158, 182, 195, 217, 262, 276). Support for the Commission's proposal for a European patent (270, 280, 287), but this system should not replace the existing systems (180, 181). The legislation relating to patents must not discriminate against small and medium-sized research centres (198). The duration of patents is too short (98, 138, 190), in particular for certain types of drugs (it takes a long time to recoup investment, especially in the case of orphan drugs) (216). Huge potential offered by the combination of three elements: biological informatics, gene technologies and networked databases (6, 197). Closing the gap with the USA and Japan will be a slow process (138). Importance of measuring the level of development of biotechnology in European countries compared to the USA (233).

3. Role of education

Education can lead to greater democratisation of the debate and should be strengthened in this area (42, 104, 113, 130, 158, 169, 192, 197, 207, 208, 214, 230, 250, 255, 261, 277). Universities must be provided with the appropriate equipment (8). Young people are a priority target group (130, 138).

4. Improving public information and consultation

The need to open up the public debate to a wider audience and keep all the stakeholders informed (121, 159, 177, 183, 188, 197, 201, 217, 262, 265). Promoting contributions from experts in various disciplines (148, 255, 295) and encouraging a plurality of points of view and positions (92, 104, 109, 110, 113, 156, 202, 213, 214, 219, 220, 224, 244, 258, 261, 285, 294), including those of experts in ethical issues (241), NGOs (113) and those directly concerned, such as patients (211, 264, 286) and disabled people (241) .

Information at local and decentralised level (113, 130, 221), available free-of-charge on the Internet (222, 315). The information must be geared to demand (211, 148, 158, 224) and also use the media (109, 113, 130, 278). The results of the tests on genetically modified crops and foodstuffs should be published (150). The risks (26, 93, 109, 150) or failures (113, 134, 234) must not be glossed over, the debate must be organised centrally or at least in a coordinated way (268). Creating a permanent forum (110). Extending the Aarhus Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environment Matters to include GMOs (134).

5. Amending the regulatory framework

Better regulation (38, 41, 148, 169, 207, 220, 289) and amending existing regulations: adopting a single legislative framework which is transparent and predictable (84, 90, 121, 132, 143, 293, 294), including authorisation procedures which are sufficiently flexible to allow the development of SMEs in this sector (84, 98, 132) and which are easily understandable for those working in it (244). No discrimination between biotechnologies and processing and production methods (299). Strengthening the role of independent agencies (169, 192), penalising abuses (247, 278), applying the rules and monitoring compliance (156, 171).

Amendments to the regulations: providing for public information and monitoring on the contained use of micro-organisms genetically modified by laboratories and factories in the context of Directive 98/81[4] (210). Stepping up the follow-up and monitoring of seed certification (110, 145); the need for legislation on pharmaceutical products to take into account orphan drugs (62), the establishment of a simplified procedure for products integrating several biotechnology applications under Regulation 2309/93 with specific details leading to guidelines or a Commission decision and validated scientifically (44, 93). Shortcomings in the protocol on testing in the field (49). The establishment of a monitoring system for the manufacture of bacteriological weapons (Member States' observance of the Treaty) (79, 90). Regulation 49/2000[5] is not operational because it does not provide for monitoring instruments in the initial phases (145). Ensuring that the Clinical Trials Directive does not penalise biotechnology products (218).

Taking the international context into account in European decisions (201, 214) and introducing a nomenclature of bio-industry activities at international level (29).

6. Eradication of diseases

Many contributions advocated stepping up research in the medical field (55, 101, 158, 182, 237, 278, 286, 294), in particular with regard to hereditary and tropical diseases (108, 193, 201, 202).

Few people were against such research, unless it violated the dignity of the person (e.g. embryo manipulation) or led to testing on animals (149, 162, 272, 291, 295). Several contributors were up in arms about the inherent reductionism of using genetic inheritance to define the totality of an individual, his behaviour, his health, etc. (94, 248); they advocated tackling the deep-rooted causes of certain social and individual dysfunctions rather than choosing only the medical route.

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4 Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms (OJ L 117 of 8.05.1990), as amended by Directive 98/81/EC of 26 October 1998 (OJ L 330 of 5.12.1998)

5 Commission Regulation (EC) 49/2000 of 10 January 2000 amending Council Regulation 1139/98 concerning the compulsory indication on the labelling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC (OJ L 6 of 11.1.2000)

7. Food safety

It is important to prevent contamination of organic crops by GMOs (38, 139, 170, 189, 202, 207, 231), but at this stage it is impossible in practice (98, 119, 120, 128, 133, 210, 220, 278). Need to develop techniques to prevent such contamination (145, 156, 176, 220). Directive 2001/18[6] is not totally satisfactory (119) and leads to too much monitoring for SMEs (240). The arrangements for the award of authorisations and certificates must be completely transparent (98, 110, 131, 134, 143, 221) and traceability guaranteed (145); ban on GM crops in certain areas (210, 313) and regulations geared to the distances between GM fields (312). Creation of a scientific review committee to examine commercialisation notifications and a risk assessment committee (92, 110, 118, 156, 210). The Commission's recent proposal to create European rules concerning GMOs is a first step towards a strong and effective European food safety authority (233, 279). Reactivating the Advisory Committee on Plant Health and Consumer Protection, whose working group on plants and seeds has not met for two years now (156).

8. Application of the precautionary principle

Applying the precautionary principle (49, 60, 78, 118, 128, 133, 191, 198, 201, 205, 220, 222, 223, 224, 258, 297); no authorisation without information, transparency of decision-making and application of scientific criteria (150) made public (210). More reference to COM 2000/1[7] in regulations (229, 233). This principle must be correctly applied by every country (128, 156, 254). International harmonisation should be promoted here, as an antidote to the strong temptation to use this principle as a way of excluding products which are undesirable at a political level (84). It must be accompanied by the principle of responsibility (128).

9. Support for developing countries

Supporting developing countries in international organisations; making them players, not just beneficiaries (281). Helping them with the production of drugs and the improvement of their healthcare systems (35, 108, 113); developing European research in a spirit of cooperation with developing countries (135, 248). Making the results of public research available to them and involving pharmaceutical firms in the lower-cost provision of drugs (113). Providing for technology transfers (135).

10. Individual freedom and restricting the use of test results

No obligation to undergo tests (88, 111, 116, 149, 158, 182, 191). No use of the results of genetic tests by insurance companies (insurance contracts) and employers (employment contracts) (150, 205), as already practised in the United Kingdom (193); guaranteeing the legal confidentiality of tests (62, 173, 182, 237, 248, 286, 294, 315), but practical proposals to achieve this are lacking.

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6 Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106 of 17.4.2001)

7 COM(2000) 1 final of 2 February 2000 on the precautionary principle.

B Points of debate

1. The benefits of biotechnology

There were about as many contributions in favour of biotechnology as against them; of the 271 contributions covered in this analysis, the number of negative ones (114) was similar to the number of positive ones (64) plus the number of conditionally positive ones (93).

The most radical positions came mainly from certain economic interest groups or NGOs; it was less common for them to be expressed by "private citizens".

The most common questions were: what are the benefits for the general public? Are these benefits, essentially of an economic nature (115, 126, 140, 152, 170, 186, 194, 225, 248, 284, 285, 298), justified in the light of the potential risks (232)? Are the choices reversible? Are the long-term risks measurable (128)? The risk of irreversibility often put forward in the individual contributions (174, 185, 189, 210) is recognised by certain scientists, given the current state of knowledge. This is why the distinction between "red" and "green" biotechnologies is advocated only by NGOs or private individuals (139, 281).

The following presentation provides only a summary of the responses received and is therefore imperfect; in particular, it fails to properly reflect all the nuances and suggestions in the contributions and the corrective and constructive solutions put forward. Moreover, these responses are not statistically relevant (number of "fors" versus number of "againsts") because of the small size of the sample.

– **Biotechnologies and developing countries:**

Some people believe that biotechnologies will help solve many problems (malnutrition, food shortages (126, 256, 257, 263, 281), human diseases, soil aridity and fertilisation (278), the fight against pests, etc.) and cut the price of pharmaceuticals (202).

Others, however, feel that biotechnologies will not solve any socio-economic or political problems (33, 186, 192, 284, 139, 301). The failings of health infrastructures and distribution networks are equally important (190). They will merely make developing countries even more dependent on the outside world (170, 232). Technological developments should meet the real needs of developing countries as expressed by the latter (102, 283). Doubt about the claim that "genetically modified organisms will contribute to increasing food production". They are a double-edged sword (according to the Director of the FAO) and require caution (18, 78, 113, 128). Some developing countries use them because of the low entry barriers and the lack of changes required to use them in practice, compared to those required for the introduction of hybrid crops (145); nevertheless, there are some obstacles associated with regulatory aspects and uncertainties about future markets (84).

– **Biotechnologies and the environment:**

Some contributions stressed the benefits of biotechnology for the environment and new sources of renewable energy (120, 163, 188, 249, 257, 278, 310). The role of the environmental protection agencies in this field should be harmonised with the USA (220). The cost of maintaining biodiversity is not justified (157). The agencies make

it possible to minimise the pollution caused by modern agricultural practices (76, 117, 121).

Other contributors thought that the dangers had been underestimated (118, 134, 194, 210, 284, 298), that monitoring had to be stricter (110, 166, 214, 258) and that most of the new problems were the result of technological progress (198). Funds should be earmarked for putting right any damage (247). Doubts about the arguments relating to the decrease in the use of pesticides/herbicides/insecticides (50, 170). Threats to biodiversity (114, 133, 194) and sensitive ecosystems (232). Certain risks, such as the risk of mutagenesis related to the place of insertion and not the transgene itself, are not yet taken into account by the evaluation bodies and in decisions relating to the release of products onto the market (32, 133). The reliability of data on secondary effects and long-term consequences is also doubtful (48, 145, 210).

– **Biotechnologies and agriculture:**

Several contributions explained the potentially enormous benefits of biotechnology, thanks to the eradication of certain pathogenic viruses in plants (76, 98, 158, 269) and organic chemistry applications (117). Reducing dependence on synthetic pesticides (76, 132, 188, 254). Agriculture is practised in an open environment, and the small-scale presence of genetically modified organisms in non-GM crops (and vice versa) is inevitable; the coexistence of GM and conventional/organic agriculture depends on this presence being accepted (84, 233). Fixing a strict but practical tolerance threshold that takes account of the inevitability of accidental contamination, especially in the case of seeds, and licence-holders', rather than farmers', obligation to make good any damage caused (232, 246).

On the other hand, many contributions warned of the dangers to organic or conventional farming (35, 95, 133, 198) and sustainable development (225), as well as the contamination of conventional plant and animal species (53, 75, 82, 118, 119, 134, 150). The genetic engineering of animals must be stopped, for ethical reasons (50, 272). Hostility to genetic modification techniques based on selection by markers which cause antibiotics to be introduced into the food chain (50, 118, 133, 152, 189). Disruption of the market and of the production of traditional seeds (102, 110, 145, 156).

– **Biotechnologies and food:**

Most of the favourable opinions related to 'functional' foods (117, 158, 208, 255), on condition that confinement techniques based on a reliable identification, authorisation, tracability and follow-up system were established (176, 211, 246).

However, many contributors were hostile in principle, because of the associated health risks and the lack of expected benefits (9, 10, 40, 70, 95, 150, 231, 284, 291, 298). GMOs could damage quality products (110) with a strong cultural element, such as wine (51), or their flavour (114).

– **Biotechnology and medicine:**

Some contributors supported medical applications because the risks were controllable (120), and any stocks could be destroyed in the event of doubts arising (35). Confined experiments present fewer risks (210, 264, 84). In-vitro diagnostics

very useful (264). Costs may become more manageable if derived products including several biotechnology applications are used (46, 113). Usefulness of certain varieties, rape enriched with amino acids, transgenic sunflowers for reducing heart disease associated with the consumption of certain oils (54, 126). Huge potential for new treatments, in particular in the area of preventive medicine for an ageing society or the prevention of genetic diseases (121, 158, 160, 181, 190, 197, 249, 262, 265, 270, 278, 314).

On the other hand, other contributions threw doubt on the benefits of turning to biotechnology to solve the problem of ageing in Europe. Would it not be better to find other solutions, e.g. encouraging immigration or more births? Warnings about allergies prompted by new pharmaceuticals (68, 118, 231); old people need care and attention more than drugs (61, 264), natural foods are better than GMOs (167).

2. Taking ethical aspects on board

A large majority of the contributions received called for ethical aspects to be taken on board:

– either at national (138, 182, 183, 205, 214, 242) or even local level, depending on the context (207), with the networking at European level of national ethical groups (204, 220). Researchers' disinterest in ethical issues has to be tackled by having them sit on ethics committees with the other representatives of civil society (199). It would be a good idea to create ethics committees and foster ethical management in companies (201, 240, 315);

– or at European level: defining the basic principles for European-level ethics (88, 191, 315) with greater involvement of the European Commission in the organisation of debates (233); the role of the European Group on Ethics should be stepped up (2, 62, 110, 121, 198, 230). This group had to be given sufficient funding (281). It must be the only reference body for all the European institutions (158) and be made up of elected representatives (92, 134, 295). It must remain independent and not represent particular countries or interest groups (133, 158, 297). It should be given the role of organising the public debate (219, 192) and following trends in public opinion (297). It should be able to contribute to the creation and adoption of joint standards. Setting up a European forum for scientific and ethical committees, associated with (204) and using the work of the Council of Europe (198). However, some contributors said that going too far (with regard to the role of the European Group on Ethics) would be counter-productive (195, 214).

3. Role of experts and risk evaluation

Many respondents wanted the position of the experts in relation to the civil society and elected representatives (Parliament) to be defined. To this end, some people (134, 190) advocated drawing a clearer distinction between risk evaluations conducted by experts ("risk assessment"), and the management of risks by the political powers-that-be ("risk management").

Rather than invoking the precautionary principle with regard to risk, it would be better to apply the proportionality principle with regard to the potential damage (143).

Risk evaluation should be stepped up, using a multidisciplinary (214), global (246) approach at European level (92, 118, 154, 191, 258, 315), with the Commission playing an important

role (258). The evaluations should be performed by organisations independent of the State and the biotechnology industry (207, 220) and should be paid for by the patent-holders (210). An advisory committee for the evaluation of biotechnologies was also suggested, with a steering committee to make proposals and gather information (65, 138), or involve consumers (295).

The criteria must be transparent and regularly updated (84, 128, 134, 244), the methodologies adapted (93) and harmonised (143). For some, examining the socio-economic and health impact had to be paramount (90, 93, 126, 128, 130, 156, 194, 281, 295, 297), including the impact on animal welfare (93, 291, 295) and on the environment (110, 166); for others, the scientific and economic aspects had to be considered separately and successively, starting with a scientific and technological risk evaluation (84, 121, 157, 176, 227). Comparisons should be made with conventional products and drugs (277). Finally, some contributors called for licences not to be subject to social or political considerations (143, 254, 293) or for a review of the current system of qualified majority voting for the management committees (84).

4. Research

The debate centres on the way of funding research, the division of responsibilities between Member States and the EU, its purpose and organisation.

– Funding and division of responsibilities

  Some contributors stressed the importance of public funding (47, 171, 188, 203), primarily under the responsibility of Member States (233) and/or according to a European approach (214, 256, 283, 315), for fundamental research (77, 84, 191, 200, 284) and pre-competitive research (287). Others emphasised the role incumbent on Member States and companies, under the subsidiarity principle (138, 148), in particular for the funding of applied research (77). Access to venture capital must be facilitated (138, 158, 195, 200, 278). Given that the European programmes account for only 5 to 10% of all research activities in Europe (67, 138), it is important to seek better harmonisation of national and regional initiatives. One person suggested the creation of a European council for fundamental research (200), whilst another wanted to limit or withdraw funding for research on human embryos (230). Information on sources of funding (and on the results) should be made public (138, 207, 217, 278, 279).

– The subjects for research

  For some, the most pressing subjects were GMOs and biotechnologies (176, 183, 278, 293), genomics for agriculture and food (188), the genomes of livestock (176), and new product tests (264).

  Others believed that it was important to use the results of molecular research to develop non-transgenic plants (98, 156, 200, 210); the choice of subjects for research depended on demand and needs (90, 224), not just the logic of researchers or commercial interests (128, 212). The research should focus on conventional and organic farming (95, 176, 247, 284), product quality and wholesomeness (145, 189), the stem cells of the human spinal column (174, 262). The need to improve our currently limited knowledge of risk evaluation (effects of organisms with prokaryotes on ecosystems and the impact on food chains (49, 56, 145). Research

must also be conducted into stepping up food safety despite limited resources, particularly in developing countries, focusing in particular on products not intended for export, rare or under-used crops, the needs of consumers with low purchasing power (47, 203).

– With regard to the organisation of research, some contributions called for large groups to be set up on the American model (192), whilst others preferred development in small enterprises and networking to form clusters (158, 208, 250, 315).

5. Organisation of the public debate

Who should be in charge of information and to what end? More information for the public (148, 220, 258), paid for by the public authorities (113, 130) or private companies (134, 210). Taking on board the results of the public debates and consultations in the regulations and international negotiations (113).

Whilst, according to some people, information campaigns should be neutral, possibly increasing the likelihood of disagreements (105, 194), others thought that they should be used to persuade (120, 169, 268), if possible in a specially adapted and targeted way (224), consumers (208) or industrialists (156); it is important to ensure that the most disadvantaged are not excluded from the benefits of biotechnology (207).

6. Specific European approach or harmonisation

Specific EU approach with regulation and defence of a particular model (115, 194), possibility of public research on specific territorial features not respected by large groups on other continents (188).

Harmonisation of patenting regulations with the USA and Japan (190) and standardisation (197, 208, 216, 227) or coordination (190).

Protection of intellectual property (121): Europe needs a less bureaucratic and onerous patenting system, along the lines of the American and Japanese systems, which removes doubts about the patentability of biotechnology inventions (84, 138, 190, 218). Mutual recognition of data and, in some cases, of decisions (84, 121, 143).

C. Points of conflict

The contributions here concern very sensitive matters relating to systems of values and ethical and moral principles (patenting the genome; economic competitiveness *versus* ethical issues) with regard to which positions tend to be more entrenched and more resistant.

1. Experiments on embryos

Embryo cell research jeopardises the principles of human dignity and integrity (45, 72, 73, 88, 106, 111, 116, 122, 123, 139, 140, 142, 146, 149, 153, 154, 162, 182, 185, 187, 191, 204, 237, 248, 281, 301, 305). Some contributors expressed their opposition in even stronger terms (50, 66, 69, 139, 144, 174, 234). One contributor claimed that the potential for differentiating between embryos was less than that for adult cells (140) and others that individual cognitive development depended much more on the cultural environment than on genetic inheritance (28, 94). Some people denounced the need for between 100 000 and 150 000 embryo cells, and therefore donors (mainly women), every year (32, 149).

2. "Patenting life"

Two points in particular were mentioned: seeds (134, 156) and human cloning (72, 88, 94, 112, 116, 121, 123, 142, 146, 149, 153, 174, 185, 204, 262, 281, 301). A patent had allegedly already been granted in Europe for the removal of human embryo cells (152).

The following elements were criticised: the lack of coherence in Directive 98/44 on what can actually be patented and the pressure exerted on the European Parliament to adopt it (36); patents on the human genome (116, 205, 288, 289) or on that of primates (291). Strengthening the legal framework for obtaining patents (36, 133). Free recording of GM seeds in the official catalogue, patenting system to protect GMOs and the absence of tests on the impact of GM plants on mammals (53).

Others said that GM patents should not be treated differently from other patents (138). "Broad" patents threatened to curb research on new diagnostic and treatment methods (204). Only real innovations, for example new genetic engineering techniques, should be protected by patents, not GMOs or hybrid plants (210).

For others, Directive 98/44 was the way forward (214) and should be implemented without delay (218, 233, 262); the current protection system is satisfactory (315), but researchers should be informed about intellectual property protection (227). Competitiveness benefits of European licences: could open up large markets outside the EU on which companies that combine several biotechnology applications could compete (46).

3. Genetically modified organisms

Some contributors called for the organisation of transport of genetically modified animals for the production of drugs (242), whilst others were explicitly against it (116, 149, 162, 174, 291). The production of genetically modified animals as well as animal testing were also rejected; the same goes for the issue of further grant of marketing authorisations for genetically modified organisms (the last licences granted under Directive 90/220/EEC date back to October 1998), with some in favour (98, 120, 176, 233, 254, 299) and others against (12, 48, 53, 58, 78, 92, 93, 95, 97, 110, 118, 133, 150, 152, 170, 194, 232, 258) .

The second generation of GMOs should not bring any substantial changes to the development of production; we should have to await the third (277) or even the fourth generation (278). Other methods (i.e. other than second-generation GMOs) are now available for producing tasty food (210). As the long-term risks are rarely known, the benefit provided by a licensed GMO should be considerable; licences already granted should be re-examined, and producers and importers should have insurance cover (210). It should be compulsory to label products containing GMOs (78).

4. Ethical issues

Ethics should be given priority, before issues of safety and competitiveness (61, 88 , 90, 106, 112, 154, 182, 187, 237, 241, 247, 274, 281, 288, 297, 315). The right to life (144, 182), the respect for human dignity (230) and the integrity of the person (45, 205), as well as freedom of choice (39, 90, 112, 139, 153, 185, 204, 207, 220, 224, 258), are all more important than research freedom. A conscientious objection clause should be introduced for certain types of research (230).

The social and economic impact should not be placed at the same level as ethical issues (148). Mention of the Charter of Fundamental Rights (90, 182). Recommendation on the terminal stage of patients. A slogan has even been proposed by the Danish Government for the future European strategy: "Making Europe a driving force for the development of life sciences and biotechnologies to encourage growth and well-being on an ethical basis" (315).

5. European trade policy

The traditional knowledge of developing countries cannot be exploited indefinitely by first-world companies; providing for a specific or additional agreement in the context of TRIPS[8] (108, 113). Shared application of the precautionary principle to avoid pointless disputes, definition of non-GMO traceability routes and trade flows, based on certified seeds and with watertight circuits; achieving specific standards for quality products in the new WTO agreement (246). The work of the International Conference for the Harmonisation of Technical Requirements for the Registration of Medicinal Products must be supported, in particular in the areas of gene therapy and comparability (218).

PART III THE USE TO BE MADE OF THE CONSULTATION

The Commission has analysed in detail the comments received as part of the public consultation to prepare for the Communication "Life Sciences and Biotechnology – a Strategy for Europe", which was adopted on 23 January 2002. It has taken note of certain questions and suggestions, which will be discussed in greater depth and tackled later on.

The consultation document will not be revised, as the Communication is meant to replace it. In this Communication, both the part relating to the strategy and that relating to the action plan, the Commission adopts a number of positions on points raised in the consultation. Furthermore, the action plan provides for concrete measures to facilitate dialogue with society, including the creation of a stakeholder forum in certain important areas where the Commission has not yet taken a position. The Commission also intends to launch an inter-institutional consultation designed to take into consideration ethical questions at European level and to evaluate the role, composition and modus operandi of the European Group on Ethics.

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[8] Trade-related aspects of intellectual property rights.

ANNEX

List of contributors by type and country

		Type of contributor
		1. Private citizens
		2. Representatives of academia
		3. NGOs and civil society organisations
		4. Biotechnology groups/private companies
		5. Public and semi-public organisations
		6. Farming organisations
		7. Consultants

		TYPE OF CONTRIBUTOR							EU Member States															NON EU
		1	2	3	4	5	6	7	B	DK	D	EL	ES	F	IRL	I	L	NL	Ö	P	FI	S	UK	
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